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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/592,011

10/22/2007

Stuart Edward Bradley

NC-10007/US

7007

38724 7590 04/17/2009

OSI PHARMACEUTICALS, INC.

41 PINELAWN ROAD

MELVILLE, NY 11747

EXAMINER

POWERS, FIONA

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

04/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/592,011	<b>Applicant(s)</b> BRADLEY ET AL.	
	<b>Examiner</b> Fiona T. Powers	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 15 to 27 is/are pending in the application.
- 4a) Of the above claim(s) 24-27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 and 22 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1, 2, 15-20 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Group I (claims 1, 2 and 15 to 23) in the reply filed on January 16, 2009 is acknowledged.

Claims 24 to 27 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 16, 2009.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 15 to 20 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, throughout the claim there is a valence problem when the variables are or include C<sub>0-4</sub>alkyl or C<sub>0-3</sub>alkyl because the substituent(s) are absent when this variable is C<sub>0</sub>alkyl.

In claim 1, line 8, C<sub>0-4</sub>alkylheoaryl is spelled incorrectly.

In claim 1, in the definition of  $R^2$  an "or" should be inserted before "hetarylC<sub>0-4</sub>alkyl-".

The proviso in claim 1 excludes compounds where  $R^3$  is C<sub>5-10</sub>cycloalkenyl when -Y-Z is as specified in the proviso (page 3, last line of amendment filed 01/16/2009). However, the definition of  $R^3$  does not include cycloalkenyl groups.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

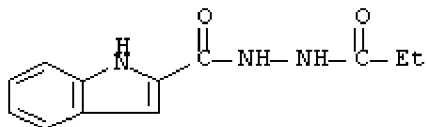
Claims 1, 2, 15, 16, 18, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Chemical Abstracts, 102:131867, 1985), cited.

The reference discloses the claimed compounds of the formula I and pharmaceutical compositions thereof wherein Y is -C(O)-; Z is C<sub>1-4</sub>alkylene;  $R^1$  and  $R^{1'}$  are hydrogen; and  $R^3$  is hydrogen. Note Registry Nos. 95446-26-7 and 95446-27-8 which are of the following structures:

Art Unit: 1626

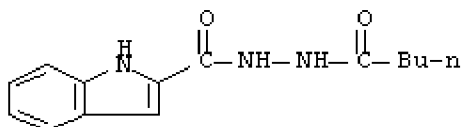
RN 95446-26-7 CAPLUS

CN 1H-Indole-2-carboxylic acid, 2-(1-oxopropyl)hydrazide (CA INDEX NAME)



RN 95446-27-8 CAPLUS

CN 1H-Indole-2-carboxylic acid, 2-(1-oxopentyl)hydrazide (CA INDEX NAME)



Claims 1, 2, 15, 17 to 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bora et al. (WO 2002/024972), cited.

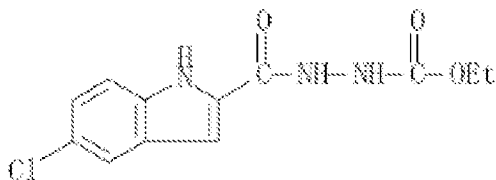
The reference discloses the claimed compounds of the formula (I) and pharmaceutical compositions thereof wherein Y is SO<sub>2</sub>; Z is a bond; R<sup>1</sup> and R<sup>1'</sup> are selected from hydrogen, halogen (e.g. 5-chloro), alkyl and alkoxy. Note the indole compounds listed on page 10, lines 28 and 31 and page 11, lines 1 to 11 and 18 to 26.

Art Unit: 1626

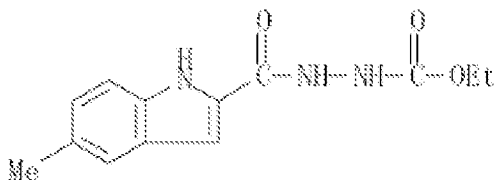
Claims 1, 2, 15, 16 and 18 to 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiremath et al. (Chemical Abstracts, 99:194890, 1983) or Sinnur et al. (Chemical Abstracts, 107:154287, 1987), cited.

Hiremath et al. disclose the claimed compounds of the formula I wherein Y is -C(O)-; Z is oxygen; R<sup>1</sup> and R<sup>1'</sup> are selected from hydrogen, 5-chloro and 5-methyl; and R<sup>3</sup> is hydrogen. Note Registry Nos. 87811-55-0 and 87811-56-1 which are of the following structures:

RN 87811-55-0 CAPLUS  
CN 1H-Indole-2-carboxylic acid, 5-chloro-, 2-(ethoxycarbonyl)hydrazide (CA INDEX NAME)



RN 87811-56-1 CAPLUS  
CN 1H-Indole-2-carboxylic acid, 5-methyl-, 2-(ethoxycarbonyl)hydrazide (CA INDEX NAME)



.

Sinnur et al. disclose the claimed compounds of the formula I wherein Y is -C(O)-; Z is a bond; R<sup>1</sup> and R<sup>1'</sup> are selected from

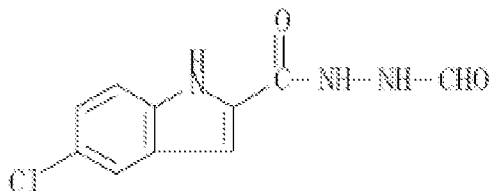
Art Unit: 1626

hydrogen and 5-chloro; and  $R^3$  is hydrogen. Note Registry Number

110448-43-6 which is shown below:

RN 110448-43-6 CAPLUS

CN 1H-Indole-2-carboxylic acid, 5-chloro-, 2-formylhydrazide (CA INDEX NAME)

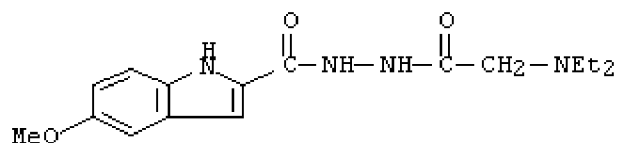


Claims 1, 2, 15, 16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mndzhoyan et al. (Chemical Abstracts, 71:12941, 1969), cited.

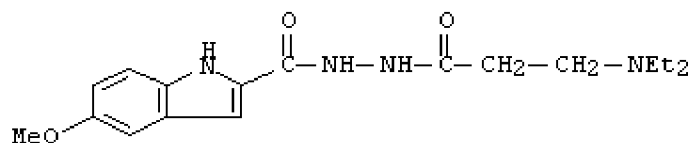
The reference discloses the claimed compounds of the formula I wherein Y is  $-C(O)-$ ; Z is NR or  $-(CH_2)_{1-2}NR-$ ; R is H or ethyl;  $R^1$  and  $R^{1'}$  are selected from hydrogen and methoxy; and  $R^3$  is H or ethyl. Note Registry Nos. 22930-48-9, 22930-49-0 and 22930-52-5 which are of the structures shown below:

Art Unit: 1626

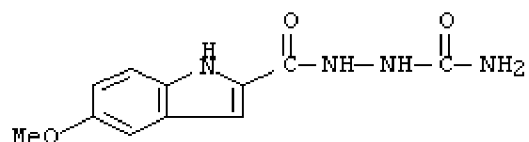
RN 22930-48-9 CAPLUS  
CN 1H-Indole-2-carboxylic acid, 5-methoxy-,  
2-[2-(diethylamino)acetyl]hydrazide (CA INDEX NAME)



RN 22930-49-0 CAPLUS  
CN 1H-Indole-2-carboxylic acid, 5-methoxy-,  
2-[3-(diethylamino)-1-oxopropyl]hydrazide (CA INDEX NAME)



RN 22930-52-5 CAPLUS  
CN 1H-Indole-2-carboxylic acid, 5-methoxy-, 2-(aminocarbonyl)hydrazide (CA  
INDEX NAME)



### ***Allowable Subject Matter***

Claims 21 and 22 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fiona T. Powers/  
Primary Examiner, Art Unit  
1626

ftp  
April 16, 2009